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10/068,905	02/07/2002	Simon Lemaire	86366	9394

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EXAMINER

KOSAR, ANDREW D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

10/068,905

### Applicant(s)

LEMAIRE ET AL.

### Examiner

Andrew D. Kosar

### Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- A. Inventions I to VI, drawn to Compounds I to III, derivatives of Compounds I to III, and pharmaceutical compositions of thereof:
- I. Claims 1,2, and 5-11, drawn to a compound of Formula I, classified in class 514, subclass 11, for example.
  - II. Claims 1,3, and 5-11, drawn to a compound of Formula II, where D= (CO), classified in class 530, subclass 300, for example.
  - III. Claims 1,3, and 5-11, drawn to a compound of Formula II, where D= (CO)-(C<sub>1</sub>-C<sub>6</sub>)alkylene, classified in class 530, subclass 300, for example.
  - IV. Claims 1,3, and 5-11, drawn to a compound of Formula II, where D= (C<sub>1</sub>-C<sub>6</sub>)alkylene, classified in class 530, subclass 300, for example.
  - V. Claims 1, and 4-11, drawn to a compound of Formula III, where E= single bond, classified in class 530, subclass 300, for example.
  - VI. Claims 1, and 4-11, drawn to a compound of Formula III, where E= (C<sub>1</sub>-C<sub>6</sub>)alkylene, classified in class 530, subclass 300, for example.

If Applicant selects an Invention from Group A, Applicant is further required to identify which single Invention in Claim 7 it reads upon, if any (i.e.- compound I-1),

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unless the Applicant provides evidence that said SEQ ID is directly connected to the species chosen from Group A and that a search of the selected Invention would reveal the SEQ ID component.

B. Inventions VII to XII, drawn to methods of use for Compounds I to III and the pharmaceutical compositions thereof:

VII. Claims 12-18, drawn to methods of COX-2 inhibition and pain management in animals using a compound of Formula I, classified in class 514, subclass 11, for example.

VIII. Claims 12-18, drawn to methods of COX-2 inhibition and pain management in animals using a compound of Formula II, where D= (CO), classified in class 530, subclass 300, for example.

IX. Claims 12-18, drawn to methods of COX-2 inhibition and pain management in animals using a compound of Formula II, where D= (CO)-(C<sub>1</sub>-C<sub>6</sub>)alkylene, classified in class 530, subclass 300, for example.

X. Claims 12-18, drawn to methods of COX-2 inhibition and pain management in animals using a compound of Formula II, where D= (C<sub>1</sub>-C<sub>6</sub>)alkylene, classified in class 530, subclass 300, for example.

XI. Claims 12-18, drawn to methods of COX-2 inhibition and pain management in animals using a compound of Formula III, where E= single bond, classified in class 530, subclass 300, for example.

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IX. Claims 12-18, drawn to methods of COX-2 inhibition and pain management in animals using a compound of Formula III, where E= (C<sub>1</sub>-C<sub>6</sub>)alkylene, classified in class 530, subclass 300, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions in Groups A and B are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The process as claimed can be practiced with another materially different product, as evidenced by the claims themselves.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for Group A is not required for Group B, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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The Examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the**

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**right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

This application contains claims directed to the following patentably distinct species of the claimed invention:

- A) Compounds of the generic Formula I with:
  - 1) Substitutions of A
  - 2) Substitutions of B
  - 3) Substitutions of EACH R<sup>1</sup>-R<sup>5</sup>
  - 4) Length of alkyl chain(s) for each occurrence of (C<sub>1</sub>-C<sub>6</sub>)
- B) Compounds of the generic Formula II with:
  - 1) Substitutions of B
  - 2) Substitutions of D
  - 3) Substitutions of Z
  - 4) Substitutions of EACH R<sup>1</sup>-R<sup>5</sup>
  - 5) Length of alkyl chain(s) for each occurrence of (C<sub>1</sub>-C<sub>6</sub>)
- C) Compounds of the generic Formula III with:
  - 1) Substitutions of B
  - 2) Substitutions of E
  - 3) Substitutions of Z

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- 4) Substitutions of EACH R<sup>1</sup>-R<sup>5</sup>
- 5) Length of alkyl chain(s) for each occurrence of (C<sub>1</sub>-C<sub>6</sub>)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-18 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571)272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith  
Primary Examiner  
Art Unit 1654

Andrew D. Kosar  
17 May 2004

A handwritten signature in black ink, appearing to read 'Patricia Leith', with a large, stylized initial 'P'.

**PATRICIA LEITH**  
**PRIMARY EXAMINER**